DETAILED ACTION

1. The examiner of record has changed.

2. This Office Action is in response to Applicant's election of Group I, Claims 70-72, 74-77, 79-80, 85 and 99 drawn to a method for treating glomerulonephritis comprising administering an IFN-beta therapeutic without traverse filed 1/22/2008. In addition, in response to species election requirement, the Applicant has further elected crescentic glomerulonephritis. Thus, the Office will examine the method of treating glomerulonephritis as it pertains to cresentic glomerulonephritis only. Claims 105, 106, 108-111, 113, 114, 119 and 133 remain withdrawn. Therefore, claims 70-72, 74-77, 79-80, 85 and 99 are pending and examined.

Information Disclosure Statement

3. The Information disclosure statements file 6/2/2006, 11/7/2006 and 2/12/2008 have been considered. Those references not considered have been indicated.

Drawings

4. The drawing filed 1/18/2005 are acknowledged.

Specification

5. The use of the trademark Sepharose (p.25), Bferon (p.35) and Image-Pro Plus (p. 58) etc. have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (p. 9 line 17). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

7. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8a. Claims 70, 71and 99 are rejected under 35 U.S.C. 102(b) as being anticipated by Udea et al. (1990).

Instant invention is drawn to a method of treating glomerulonephritis in mammals (humans) by administering interferon-β.

Udea et al. teach the administration of interferon-β to treat glomerulonephritis in patients (abstract). The reference also teaches that these patients had membranous glomerulonephritis and proliferative glomerulonephritis. The crescent formation in patients is disclosed in pg. 1156. Thus, disclosing the treatment of crescentic glomerulonephritis using interferon-β. This meets the limitation of claims 70, 71 and 99. The reference teaches that the administration of interferon-β results in improvement of

proteinuria (abstract). Therefore, claims 70, 71 and 99 are rejected under 35 U.S.C. 102(b) as being anticipated by Udea et al. (1990).

8b. Claims 70, 72, 74 and 79 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Udea et al. (1990).

Instant invention is drawn to a method of treating glomerulonephritis in mammals (humans) by administering human interferon-β.

Udea et al. teach the administration of interferon-β to treat glomerulonephritis in patients (abstract). Although, the abstract does not indicate, it is assumed that the interferon-β administered is from human and of mature form. Furthermore it is assumed that it is interferon-β-1a that is administered because it is the mature form. It is noted that the Office is waiting on the translation of this document. However, if the interferon-β administered is not mature human form it would be obvious to administer human interferon-β to avoid immune reaction. Further, it is the mature interferon-β (166 amino acids) which is commonly used for administration. This interferon-β is also known as interferon-β-1a. Therefore, claims 70, 72, 74 and 79 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Udea et al. (1990).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9a. Claims 70-72, 74-77, 79, 80, 85 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Udea et al. (1990) in view of Pedersen et al. (U. S Patent No. 6, 531, 122).

Instant invention is drawn to a method of treating glomerulonephritis in mammals (humans) by administering interferon-β.

The teachings Udea et al. (1990) are disclosed above in paragraph 7a. However, the reference does not teach interferon-β of SEQ ID NO: 4.The reference also does not teach a glycosylated interferon-β or pegylated interferon-β. In addition, the Udea et al. reference does not disclose interferon-β-1b.

Pedersen et al. teach various interferon-β preparations. The Pedersen reference teaches mature interferon-β of SEQ ID NO: 2 (columns 1- 3) which is identical to SEQ ID NO: 4 of the instant invention. This meets the limitations of claims 75 and 76. The glycosylation of interferon-β is disclosed (column 2). This meets the limitation of claim 77. Interferon-β-1a and interferon-β-1b are also disclosed (column 2) meeting the limitation of claims 79 and 80. The pegylation of interferon-β is also discussed (column 4 and entire patent).

Therefore, it would have been *prima facie* obvious at the time of the invention to modify the treatment methods of Udea et al. (1999) to treat glomerulonephritis in mammals (humans) by administering various interferon-β molecules as disclosed in Pedersen et al. One of ordinary skill in the art would have been motivated to use the methods of Udea et al. to treat glomerulonephritis by administering modified interferon-β because Pedersen et al. disclose that mature modified interferon-β functions similar to unmodified mature interferon-β.

Further, there is reasonable expectation of success because Udea et al. reference clearly teaches that interferon-β improves the clinical outcome of glomerulonephritis patients specifically with the reduction of proteinuria. The rationale for using modified interferon-β of Pedersen et al. is to reduce the allergenicity (column 2) and increase the circulating half life of the protein. One of ordinary skill in the art would have been motivated use the dosages used in Udea et al. because they are clinically effective. Therefore, the instant invention is *prima facie* obvious over Udea et al. (1990) in view of Pedersen et al. (U. S Patent No. 6, 531, 122).

Relevant Art

10. Schwarting reference teaches the use of interferon-β in the treatment of systemic lupus erythematodes. It also discloses the improvement of glomerulonephritis.

Conclusion

11. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
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/Jegatheesan Seharaseyon, Ph.D/
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